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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,604	05/31/2000	Andrew J. Dannenberg	CRF D-2165	9421

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 30

Application Number: 09/554,604
Filing Date: May 31, 2000
Appellant(s): DANNENBERG, ANDREW J.

Eric Spector
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to paper No. 27, the submission of publication on August 20, 2003.

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1. Pursuant to the Remand under 37 CFR 1.193(b)(1) by the Board of Patent Appeals and Interferences on August 29, 2003, a supplemental Examiner's Answer is set forth below:

appellants' arguments and the article of Yamamoto submitted August 20, 2003 have been fully considered, but are not persuasive.

2. The arguments are related to one of the issues involved in the appeal, i.e., whether consideration of art as a whole leads away from the invention (page 6 of the Appeal brief), or whether the cited references provides a reasonable expectation of success for the claimed invention. Applicants cite Yamamoto et al. reference as new evidence for supporting the arguments that there is no reasonable expectation for success for the claimed invention, or, more specifically, there is no reasonable expectation for success for COX-2 inhibitor to treat disorders which have been treated successfully by non-selected COX inhibitor. The specific evidence cited by applicants is: "Yamamoto et al had to carry out testing for a selective inhibitor of COX-2 to determine utility even though nonselective COX inhibitors has [sic] previously been found useful for the same purpose." (page 2 of the submission). The arguments are found not persuasive.

3. The examiner notes that Yamamoto reference was published in July 2003, more than five years after the effective filing date of the instant application. One of ordinary skill in the art, at the time of the invention was made, could not reach into the future for the disclosure by Yamamoto et al.

Further, the legal standard for supporting an obvious rejection is "reasonable expectation of success," not a *prediction*, nor a *confirmed fact*. Therefore, carrying out a test to *confirm* a reasonable expectation does not negate the presence of the reasonable expectation. In fact, Yamamoto et al recite the known facts, i.e., COX-1 is constitutively expressed in tissues, and

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COX-2 is expressed in pathological conditions, and strongly suggests that COX-2 inhibitors would be reasonably expected to be useful for treating disorders that have been treated by non-selective COX inhibitors. Yamamoto et al. *confirmed* such expectation (see page 556, the last paragraph, page 564, discussion). Yamamoto et al reference does not provide evidence in supporting appellants' allegation that there is "no reasonable expectation of success."


Yamamoto et al. provide no evidence affecting the obvious rejection set forth in paper No. 10.

As stated in the examiner's answer (paper No. 20): "Possessing the knowledge that cyclooxygenase-2 inhibitor is useful for treating inflammatory diseases generally and biliary cirrhosis specifically, an inflammatory liver disorder, one of ordinary skill in the art would have reasonable expected that cyclooxygenase-2 inhibitor would be useful for treating hepatitis, an inflammatory liver disorder. Further, the claimed compounds, old and well-known cyclooxygenase-2 inhibitors, would have been reasonably expected to be useful for treating cirrhosis caused by alcohol since cyclooxygenase-2 inhibitor is generally known to be useful for treating biliary cirrhosis."

For the above reasons, it is believed that the rejections should be sustained.

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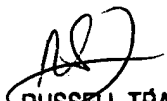
Respectfully submitted,

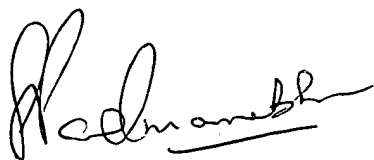

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December 3, 2003

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12/8/03